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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Julie Straub, David Altreuter, Howard Bernstein, Donald E. Chickering III, Sarwat Khattak, and Greg Randall

Serial No.: 10/053,929 Art Unit: Not Yet Assigned

Filed: January 22, 2002 Examiner: Not Yet Assigned

For: *POROUS DRUG MATRICES AND METHODS OF MANUFACTURE THEREOF*

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including twelve (12) pages of Form PTO-1449. The documents cited below were cited by or submitted to the Patent Office in Application Serial No. 09/433,486, filed November 4, 1999, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S. Patents

Number	Issue Date	Patentee	Class/Subclass
5,382,437	01-17-1995	Ecanow	424/499
5,468,598	11-21-1995	Miller et al.	430/372
5,470,583	11-28-1995	Na, et al.	424/489
5,500,331	03-19-1996	Czekai, et al.	430/449
5,510,118	04-23-1996	Bosch, et al.	424/489
5,513,803	05-07-1996	Czekai, et al.	241/16
5,518,187	05-21-1996	Bruno, et al.	241/5
5,518,738	05-21-1996	Eickhoff, et al.	424/493
5,534,270	07-09-1996	De Castro	424/490
5,552,160	09-03-1996	Liverside et al.	424/489
5,560,932	10-01-1996	Bagchi, et al.	424/489
5,565,188	10-15-1996	Wong, et al.	424/9.411
5,569,448	10-29-1996	Wong, et al.	424/9.45
5,571,536	11-05-1996	Eickhoff, et al.	424/489
5,580,579	12-03-1996	Ruddy, et al.	424/489
5,587,143	12-24-1996	Wong	424/9.1
5,591,456	01-07-1997	Franson, et al.	424/494
5,609,998	03-11-1997	Texter, et al.	430/449
5,622,279	09-02-1997	Czekai, et al.	241/21
5,622,938	04-22-1997	Wong	514/35
5,657,931	08-19-1997	Nair, et al.	241/21
5,662,883	09-02-1997	Bagchi, et al.	424/9.4
5,665,331	09-09-1997	Bagchi, et al.	424/9.45
5,716,642	02-10-1998	Bagchi, et al.	424/489
5,718,919	02-17-1998	Ruddy, et al.	424/489
5,747,001	05-05-1998	Wiedman, et al.	424/45
5,762,961	06-09-1998	Roser et al.	424/464
5,919,434	07-06-1999	Dugstad, et al.	424/9.52
5,976,574	11-02-1999	Gordon, et al.	424/489
5,985,285	11-16-1999	Titball, et al.	424/234.1
6,001,336	12-14-1999	Gordon	424/46

Foreign Patent Documents

Number	Publication Date	Patentee	Country
2 136 704	05-28-1995	Hoechst Aktiengesellschaft	CA
37 13 326 A1	10-29-1987	BASF AG	DE
0 655 237 A1	05-31-1995	Hoechst Aktiengesellschaft	EP
1 265 615	03-01-1972	Boehringer Mannheim G.M.B.H.	GB
WO 99/56731 A1	11-11-1999	Acusphere, Inc.	PCT

WO 98/31346 A1	07-23-1998	Massachusetts Institute of Technology	PCT
WO 98/51282 A1	11-19-1998	Imarx Pharmaceutical Corp.	PCT

Publications

ADEYEYE & PRICE, "Chemical, dissolution stability and microscopic evaluation of suspensions of ibuprofen and sustained release ibuprofen-wax microspheres," *J. Microencapsul.* 14(3):357-77 (1997).

AHN, et al., "Enhancement of bioavailability of ketoprofen using dry elixir as a novel dosage form," *Drug Dev. Ind. Pharm.* 24(7):697-701 (1998).

AKADE, et al., "Influence of polyethylene glycol 6000 and mannitol on the in-vitro dissolution properties of nitrofurantoin by the dispersion technique," *Pharmazie.* 41(12):849-51 (1986).

AKBARIEH & TAWASHI, "Morphic features of solid particles after micronization in the fluid energy mill," *Int. J. Pharm.* 35:81-89 (1987).

ALLEN, et al., "Dissolution rates of corticosteroids utilizing sugar glass dispersions," *J. Pharm. Sci.* 66(4):494-97 (1977).

ANSEL, et al., Pharmaceutical Dosage Forms and Drug Delivery Systems, 6th Ed., (Williams & Wilkins 1995).

APPEL & ZENTNER, "Use of modified ethylcellulose lattices for microporous coating of osmotic tablets," *Pharm. Res.* 8(5):600-04 (1991).

ARIAS, et al., "The application of solid dispersion technique with D-mannitol to the improvement in oral absorption of triamterene," *J. Drug Target.* 2(1):45-51 (1994).

ARIAS, et al., "Dissolution properties and in vivo behaviour of triamterene in solid dispersions with polyethylene glycols," *Pharm. Acta. Helv.* 71(4):229-35 (1996).

ARTEAGA, et al., "Dissolution velocity of different calcium preparations used in the clinical field," *Rev. Med. Chil.* 124(11):1325-33 (1996).

BADIGER, et al., "Porogens in the preparation of microporous hydrogels based on poly(ethylene oxides)," *Biomaterials* 14:1059-63 (1993).

BODMEIER & PAERATAKUL, "Spherical agglomerates of water-insoluble drugs," *J. Pharm. Sci.* 78(11):964-67 (1989).

BORGSTRÖM, et al., "In vitro and in vivo evaluation of controlled-release and enteric-coated formulations of sodium salicylate," *Biopharm. Drug Dispos.* 5(3):261-72 (1984).

BUCKTON, et al., "The effect of comminution technique on the surface energy of a powder," *Int. J. Pharm.* 47:121-28 (1998).

CARDORNIGA, et al., "In vitro evaluation of the dissolution rate of crystalline suspensions destined to intramuscular administration," *Eur. J. Drug Metab. Pharmacokinet.* Spec No 3:379-84 (1991).

CHAUMEIL, "Micronization: a method of improving the bioavailability of poorly soluble drugs," *Meth. Find Exp. Clin. Pharmacol.* 20(3):211-15 (1998).

CHEN & HAO, "Factors affecting zero-order release kinetics of porous gelatin capsules," *Drug Dev. Ind. Pharm.* 24(6):557-62 (1998).

CHEN & HAO, "In vitro performance of floating sustained-release capsule of verapamil," *Drug. Dev. Ind. Pharm.* 24(11):1067-72 (1998).

CHIOU & RIEGELMAN, "Oral absorption of griseofulvin in dogs: increased absorption via solid dispersion in polyethylene glycol 6000," *J. Pharm. Sci.* 59(7):937-42 (1970).

CHIOU & RIEGELMAN, "Pharmaceutical applications of solid dispersion systems," *J. Pharm. Sci.* 60:1281-1302 (1971).

CHIOU, et al., "Enhancement of dissolution rates of poorly water-soluble drugs by crystallization in aqueous surfactant solutions I: Sulfathiazole, Prednisone, and Chloramphenicol," *J. Pharm. Sci.* 65:1702-04 (1976).

CHRISTENSEN, et al., "Storage of polyvinylpyrrolidone (PVP) in tissues following long-term treatment with a PVP-containing vasopressin preparation," *Act. Med. Scand.* 204:295-98 (1978).

CORRIGAN & HOLOHAN, "Amorphous spray-dried hydroflumethiazide-polyvinylpyrrolidone systems: physiochemical properties," *J. Pharm. Pharmacol.* 36(4):217-21 (1984).

DE ALMEIDA, et al., "Modeling dissolution of sparingly soluble multisized powders," *J. Pharm. Sci.* 86:726-732 (1997).

DORDUNOO, et al., "Physical stability of solid dispersions containing triamterene or temazepam in polyethylene glycols," *J. Pharm. Pharmacol.* 49(4):390-96 (1997).

DRESSMAN & FLEISHER, "Mixing-tank model for predicting dissolution rate control or oral absorption," *J. Pharm. Sci.* 75(2):109-16 (1986).

EICHMAN & ROBINSON, "Mechanistic studies on effervescent-induced permeability enhancement," *Pharm. Res.* 15(6):925-30 (1998).

EL-FATTAH, et al., "Enhancement of dissolution rate of hydrochlorothiazide via solid dispersion," *Pharmazie.* 41(11):790-93 (1986).

FEINSTEIN & SCIARRA, "Development and evaluation of a dexamethasone timed-release aerosol formulation," *J. Pharm. Sci.* 64:408-13 (1975).

FENIMORE & LOY, "Injectible dispersion of Δ^9-tetrahydrocannabinol in saline using polyvinyl pyrrolidone," *J. Pharm. Pharmac.* 23:310- (1971).

FORD, "The current status of solid dispersions," *Pharm. Act. Helv.* 61:69-88 (1986).

FREITAS & MÜLLER, "Spray-drying of solid lipid nanoparticles (SLN^{TM})," *Eur. J. Pharm. Biopharm.* 46(2):145-51 (1998).

GALIA, et al., "Evaluation of various dissolution media for predicting *in vivo* performance of class I and II drugs," *Pharm. Res.* 15(5):698-705 (1998).

GENTA, et al., "Improvement of dexamethasone dissolution rate from spray-dried chitosan microspheres," *S.T.P. Pharma Sciences* 5(3):202-07 (1995).

GHOSH, et al., "Product development studies on the tablet formulation of ibuprofen to improve bioavailability," *Drug Dev. Ind. Pharm.* 24(5):473-77 (1998).

GIUNCHEDI, et al., "A swellable polymer as carbamazepine dissolution rate enhancer," *Boll. Chim. Farm.* 129(1):17-20 (1990).

GRIJSEELS, et al., "Dissolution at porous interfaces VI: Multiple pore systems," *J. Pharm. Sci.* 73(12):1771-74 (1984).

GRIJSEELS, et al., "Dissolution at porous interfaces VI: Pore effects in natural convection flow," *Pharmaceutisch Weekblad Scienific Edition* 5:88-94 (1983).

HAMMAD & MÜLLER, "Increasing drug solubility by means of bile salt-phosphatidylcholine-based mixed micelles," *Eur. J. Pharm. Biopharm.* 46(3):361-67 (1998).

HASTEDT & WRIGHT, "Diffusion in porous materials above the percolation threshold," *Pharm. Res.* 7(9):893-901 (1990).

HIRSCHBERG, et al., "Oral absorption of CGS-20625, an insoluble drug, in dogs and man," *J. Pharmacokinet. Biopharm.* 23(1):11-23 (1995).

HONG, et al., "Accelerated oral absorption of gliclazide in human subjects from a soft gelatin capsule containing a PEG 400 suspension of gliclazide," *J. Controlled Release* 51(2-3):185-92 (1998).

IMAI, et al., "Enhancement of the dissolution rates of poorly water-soluble drugs by water-soluble gelatin," *Chem. Pharm. Bull.* 37(8):2251-52 (1989).

IMAI, et al., "Rapidly absorbed solid oral formulations of ibuprofen using water-soluble gelatin," *J. Pharm. Pharmacol.* 42(9):615-19 (1990).

JU, et al., "Drug release from hydrophilic matrices. 1. New scaling laws for predicting polymer and drug release based on the polymer disentanglement concentration and the diffusion layer," *J. Pharm. Sci.* 84(12):1455-63 (1995).

KAGKADIS, et al., "A freeze-dried injectable form of ibuprofen: development and optimisation using response surface methodology," *PDA J. Pharm. Sci. Technol.* 50(5):317-23 (1996).

KAI, et al., "Oral absorption improvement of poorly soluble drug using solid dispersion technique," *Chem. Pharm. Bull.* 44(3):568-71 (1996).

KANENIWA & WATARI, "Dissolution of slightly soluble drugs. I. Influence of particle size on dissolution behavior," *Chem. Pharm. Bull.* 22:1699-705 (1974).

KAUR, et al., "Comparison of polyethylene glycol and polyoxyethylene stearate as excipients for solid dispersion systems of griseofulvin and tolbutamide II: dissolution and solubility studies," *J. Pharm. Sci.* 69(11):1321-26 (1980).

KAWASHIMA, et al., "Improvement of solubility and dissolution rate of poorly water-soluble salicylic acid by a spray-drying technique," *J. Pharm. Pharmacol.* 27(1):1-5 (1975).

KHAN & JIABI, "Preparation, characterization, and dissolution studies of ibuprofen solid dispersions using polyethylene glycol (PEG), talc, and PEG-talc as dispersion carriers," *Drug Dev. Ind. Pharm.* 24(5):455-62 (1998).

KHAN, et al., "Controlled release coprecipitates: formulation considerations," *J. Control. Rel.* 37:131-41 (1995)

KIM & YOON, "Development of digoxin dry elixir as a novel dosage form using a spray-drying technique," *J. Microencapsul.* 12(5):547-56 (1995).

KINCL, et al., "Increasing oral bioavailability of progesterone by formulation," *J. Steroid. Biochem.* 9(1):83-84 (1978).

KONDO, et al., "Pharmacokinetics of a micronized, poorly water-soluble drug, HO-221, in experimental animals," *Biol. Pharm. Bull.* 16(8):796-800 (1993).

KUBO & MIZOBE, "Improvement of dissolution rate and oral bioavailability of a sparingly water-soluble drug, (+/-)-5-[[2-(2-naphthalenylmethyl)-5-benzoxazolyl]-methyl]- 2, 4-thiazolidinedione, in co-ground mixture with D-mannitol," *Biol. Pharm. Bull.* 20(4):460-63 (1997).

KUBO, et al., "Enhancement of oral bioavailability and pharmacological effect of 1-(3,4-dimethoxyphenyl)-2,3-bis(methoxycarbonyl)-4-hydroxy-6,7,8- trimethoxynaphthalene (TA-7552), a new hypocholesterolemic agent, by micronization in co-ground mixture with D-mannitol," *Biol. Pharm. Bull.* 19(5):741-47 (1996).

LEE, et al., "Mathematical modelling of the release of drug from porous, nonswelling transdermal drug-delivery devices," *IMA J. Math. Appl. Med. Biol.* 15(2):135-63 (1998).

LEMOS-SENNA, et al., "Evaluation of the hydrophobic drug loading characteristics in nanoprecipitated amphiphillic cyclodextrin nanospheres," *Pharm. Dev. Tech.* 3:85-94 (1998).

LEUCUTA, et al., "The kinetics of nifefipine release from porous hydrophilic matrices and the pharmacokinetics in man," *Pharmazie* 43:845-48 (1988).

LIN, et al., "Improved oral absorption of L-365260, a poorly soluble drug," *Biopharm. Drug Dispos.* 17(1):1-15 (1996).

LIN, et al., "Preparation of enteric-coated microspheres of *Mycoplasma hyopneumoniae* vaccine with cellulose acetate phthalate: (II). Effect of temperature and pH on the stability and release behaviour of microspheres," *J. Microencapsul.* 8(4):537-45 (1991).

MARTINDALE, The Extra Pharmacopoeia, 711 Dissolution, pp. 1791-92, 30th Ed. (The Pharmaceutical Press, London 1993).

MASON & WINER, "Kinetics of aspirin, salicylic acid, and salicyluric acid following oral administration of aspirin as a tablet and two buffered solutions," *J. Pharm. Sci.* 70(3):262-65 (1981).

MIGLIARESI, et al., "Physical characterization of microporous poly(2-hydroxyethyl methacrylate) gels," *J. Biomed. Mater. Res.* 15:307-17 (1981).

MISHRA & YALKOWSKY, "A flat circular hole device for zero-order release of drugs: characterization of the moving dissolution boundary," *Pharm. Res.* 7(11):1195-97 (1990).

MORRIS, et al., "Structural properties of polyethylene glycol-polysorbate 80 mixture, a solid dispersion vehicle," *J. Pharm. Sci.* 81(12):1185-88 (1992).

NAJIB, et al., "The adsorption of hydrophilic polymers at the liquid-solid interface," *J. Pharm. Pharmac.* 29:43P (1977).

NISHIMURA, et al., "Dosage form design for improvement of bioavailability of levodopa VI: formulation of effervescent enteric-coated tablets," *J. Pharm. Sci.* 73(7):942-46 (1984).

NYSTRÖM, et al., "Dissolution rate measurements of sparingly soluble compounds with the Coulter Counter model TAII," *J. Pharm. Pharmacol.* 37(4):217-21 (1985).

NYSTRÖM & WESTERBERG, "The use of ordered mixtures for improving the dissolution rate of low solubility compounds," *J. Pharm. Pharmacol.* 38(3):161-65 (1986).

OTSUKA, et al., "Hygroscopic stability and dissolution properties of spray-dried solid dispersions of furosemide with Eudragit," *J. Pharm. Sci.* 82(1):32-38 (1993).

PACE, et al., "Novel injectable formulations of insoluble drugs," *Pharmaceutical Technology* 116-34 (March 1999).

PILLAY & FASSIHI, "A new method for dissolution studies of lipid-filled capsules employing nifedipine as a model drug," *Pharm. Res.* 16(2):333-37 (1999).

REDDY, et al., "Dissolution characteristics and oral absorption of digitoxin and digoxin coprecipitates," *J. Pharm. Sci.* 65(12):1753-58 (1976).

RIDOLFO, et al., "Benoxaprofen, a new anti-inflammatory agent: particle-size effect on dissolution rate and oral absorption in humans," *J. Pharm. Sci.* 68(7):850-52 (1979).

SAANO, et al., "Relative pharmacokinetics of three oral 400 mg ibuprofen dosage forms in healthy volunteers," *Int. J. Clin. Pharm. Ther. Toxic.* 29:381-85 (1991).

SCHRÖDER & SABEL, "Nanoparticles, a drug carrier system to pass the blood-brain barrier, permit central analgesic effects of i.v. dalargin injections," *Brain Research* 710:121-24 (1996).

SERAJUDDIN, et al., "Improved dissolution of a poorly water-soluble drug from solid dispersions in polyethylene glycol: polysorbate 80 mixtures," *J. Pharm. Sci.* 79(5):463-64 (1990).

SERAJUDDIN, et al., "Effect of vehicle amphiphilicity on the dissolution and bioavailability of a poorly water-soluble drug from solid dispersions," *J. Pharm. Sci.* 77(5):414-17 (1988).

SERAJUDDIN, et al., "Water migration from soft gelatin capsule shell to fill material and its effect on drug solubility," *J. Pharm. Sci.* 75(1):62-64 (1986).

SUZUKI & SUNADA, "Comparison of nicotinamide, ethylurea, and polyethylene glycol as carriers for nifedipine solid dispersion systems," *Chem. Pharm. Bull.* 45:1688-93 (1997).

SUZUKI & SUNADA, "Influence of water-soluble polymers on the dissolution of nifedipine solid dispersions with combined carriers," *Chem. Pharm. Bull.* 46:482-87 (1998).

SWEETANA & AKERS, "Solubility principles and practices for parenteral drug dosage form development," *PDA J. Pharm. Sci. Technol.* 50(5):330-42 (1996).

TAKENAKA, et al., "Preparations of solid particulates of theophylline--ethylenediamine complex by a spray-drying technique," *J. Pharm. Sci.* 71(8):914-19 (1982).

TAKEUCHI, et al., "Enhancement of the dissolution rate of a poorly water-soluble drug (tolbutamide) by a spray-drying solvent deposition method and disintegrants," *J. Pharm. Pharmacol.* 39(10):769-73 (1987).

TASIĆ, et al., "The influence of beta-cyclodextrin on the solubility and dissolution rate of paracetamol solid dispersions," *J. Pharm. Pharmacol.* 44(1):52-55 (1992).

TINGSTAD, et al., "Dissolution rate studies. III. Effect of type and intensity of agitation on dissolution rate," *J. Pharm. Sci.* 62(2):293-97 (1973).

TORRADO, et al., "Egg albumin microspheres containing paracetamol for oral administration. I. In vitro characterization," *J. Microencapsul.* 7(4):463-70 (1990).

TRAUE, et al., "Spray products of sparingly soluble drugs. 1. In vitro study of spray products of nitrazepam in a starch hydrolysis product," *Pharmazie.* 43(5):368-69 (1988).

VÉLAZ, et al., "Effect of PEG 4000 on the dissolution rate of naproxen," *Eur. J. Drug Metab. Pharmacokinet.* 23(2):103-08 (1998).

VENKATARAM & ROGERS, "Characteristics of drug-phospholipid coprecipitates I: Physical properties and dissolution behavior of griseofulvin-dimyristoylphosphatidylcholine systems," *J. Pharm. Sci.* 73(6):757-61 (1984).

VUDATHALA & ROGERS, "Dissolution of fludrocortisone from phospholipid coprecipitates," *J. Pharm. Sci.* 81(3):282-86 (1992).

WAN, et al., "Plasticizers and their effects on microencapsulation process by spray-drying in an aqueous system," *J. Microencapsul.* 9(1):53-62 (1992).

WESTERBERG, et al., "Physicochemical aspects of drug release. IV. The effect of carrier particle properties on the dissolution rate from ordered mixtures," *Int. J. Pharm.* 28:23-31 (1986).

YAMAOKA, et al., "Comparison of body distribution of poly(vinyl alcohol) with other water-soluble polymers after intravenous administration," *J. Pharm. Pharmacol.* 47:479-86 (1995).

YAMAOKA, et al., "Fate of water-soluble polymers administered via different routes," *J. Pharm. Sci.* 84(3):349-54 (1995).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

Patrea L. Pabst
Reg. No. 31,284

Dated: June 12, 2002

HOLLAND & KNIGHT LLP
One Atlantic Center
1201 West Peachtree Street, N.E.
Suite 2000
Atlanta, Georgia 30309-3400
404-817-8473
FAX 404-817-8588
www.hklaw.com

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Application Number	10/053,929
Filing Date	January 22, 2002
First Named Inventor	Julie Straub
Group Art Unit	
Examiner Name	
Attorney Docket Number	ACU 109 CIP

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	US Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		5,382,437		Ecanow	01-17-1995	COPY OF PAPERS ORIGINALLY FILED
		5,468,598		Miller et al.	11-21-1995	
		5,470,583		Na, et al.	11-28-1995	
		5,500,331		Czekai, et al.	03-19-1996	
		5,510,118		Bosch, et al.	04-23-1996	RECEIVED
		5,513,803		Czekai, et al.	05-07-1996	
		5,518,187		Bruno, et al.	05-21-1996	JUN 27 2002
		5,518,738		Eickhoff, et al.	05-21-1996	
		5,534,270		De Castro	07-09-1996	TECH CENTER 1600/2900
		5,552,160		Liverside et al.	09-03-1996	
		5,560,932		Bagchi, et al.	10-01-1996	
		5,565,188		Wong, et al.	10-15-1996	
		5,569,448		Wong, et al.	10-29-1996	
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		5,587,143		Wong	12-24-1996	

FOREIGN PATENT DOCUMENTS

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		CA	2 136 704		Hoechst Aktiengesellschaft	05-28-1995		
		DE	37 13 326	A1	BASF AG	10-29-1987		
		EP	0 655 237	A1	Hoechst Aktiengesellschaft	05-31-1995		
		GB	1 265 615		Boehringer Mannheim G.M.B.H.	03-01-1972		
		WO	99/56731	A1	Acusphere, Inc.	11-11-1999		

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		5,609,998		Texter, et al.	03-11-1997	
		5,622,279		Czekai, et al.	09-02-1997	
		5,622,938		Wong	04-22-1997	
		5,657,931		Nair, et al.	08-19-1997	
		5,662,883		Bagchi, et al.	09-02-1997	
		5,665,331		Bagchi, et al.	09-09-1997	
		5,716,642		Bagchi, et al.	02-10-1998	
		5,718,919		Ruddy, et al.	02-17-1998	
		5,747,001		Wiedman, et al.	05-05-1998	
		5,762,961		Roser et al.	06-09-1998	
		5,919,434		Dugstad, et al.	07-06-1999	
		5,976,574		Gordon, et al.	11-02-1999	
		5,985,285		Titball, et al.	11-16-1999	
		6,001,336		Gordon	12-14-1999	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Office.[3]	Number[4]	Kind Code[5] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		WO	98/31346	A1	Massachusetts Institute of Technology	07-23-1998		
		WO	98/51282	A1	Imarx Pharmaceutical Corp.	11-19-1998		

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Filing Date	January 22, 2002
First Named Inventor	Julie Straub
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		ADEYEYE & PRICE, "Chemical, dissolution stability and microscopic evaluation of suspensions of ibuprofen and sustained release ibuprofen-wax microspheres," *J. Microencapsul.* 14(3):357-77 (1997).	
		AHN, et al., "Enhancement of bioavailability of ketoprofen using dry elixir as a novel dosage form," *Drug Dev. Ind. Pharm.* 24(7):697-701 (1998).	
		AKADE, et al., "Influence of polyethylene glycol 6000 and mannitol on the in-vitro dissolution properties of nitrofurantoin by the dispersion technique," *Pharmazie.* 41(12):849-51 (1986).	
		AKBARIEH & TAWASHI, "Morphic features of solid particles after micronization in the fluid energy mill," *Int. J. Pharm.* 35:81-89 (1987).	
		ALLEN, et al., "Dissolution rates of corticosteroids utilizing sugar glass dispersions," *J. Pharm. Sci.* 66(4):494-97 (1977).	
		ANSEL, et al., Pharmaceutical Dosage Forms and Drug Delivery Systems, 6th Ed., (Williams & Wilkins 1995).	
		APPEL & ZENTNER, "Use of modified ethylcellulose lattices for microporous coating of osmotic tablets," *Pharm. Res.* 8(5):600-04 (1991).	
		ARIAS, et al., "Dissolution properties and in vivo behaviour of triamterene in solid dispersions with polyethylene glycols," *Pharm. Acta. Helv.* 71(4):229-35 (1996).	
		ARIAS, et al., "The application of solid dispersion technique with D-mannitol to the improvement in oral absorption of triamterene," *J. Drug Target.* 2(1):45-51 (1994).	
		ARTEAGA, et al., "Dissolution velocity of different calcium preparations used in the clinical field," *Rev. Med. Chil.* 124(11):1325-33 (1996).	

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		BADIGER, et al., "Porogens in the preparation of microporous hydrogels based on poly(ethylene oxides)," *Biomaterials* 14:1059-63 (1993).	
		BODMEIER & PAERATAKUL, "Spherical agglomerates of water-insoluble drugs," *J. Pharm. Sci.* 78(11):964-67 (1989).	
		BORGSTRÖM, et al., "In vitro and in vivo evaluation of controlled-release and enteric-coated formulations of sodium salicylate," *Biopharm. Drug Dispos.* 5(3):261-72 (1984).	
		BUCKTON, et al., "The effect of comminution technique on the surface energy of a powder," *Int. J. Pharm.* 47:121-28 (1998).	
		CARDORNIGA, et al., "In vitro evaluation of the dissolution rate of crystalline suspensions destined to intramuscular administration," *Eur. J. Drug Metab. Pharmacokinet.* Spec No 3:379-84 (1991).	
		CHAUMEIL, "Micronization: a method of improving the bioavailability of poorly soluble drugs," *Meth. Find Exp. Clin. Pharmacol.* 20(3):211-15 (1998).	
		CHEN & HAO, "Factors affecting zero-order release kinetics of porous gelatin capsules," *Drug Dev. Ind. Pharm.* 24(6):557-62 (1998).	
		CHEN & HAO, "In vitro performance of floating sustained-release capsule of verapamil," *Drug. Dev. Ind. Pharm.* 24(11):1067-72 (1998).	
		CHIOU & RIEGELMAN, "Oral absorption of griseofulvin in dogs: increased absorption via solid dispersion in polyethylene glycol 6000," *J. Pharm. Sci.* 59(7):937-42 (1970).	
		CHIOU & RIEGELMAN, "Pharmaceutical applications of solid dispersion systems," *J. Pharm. Sci.* 60:1281-1302 (1971).	

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		CHIOU, et al., "Enhancement of dissolution rates of poorly water-soluble drugs by crystallization in aqueous surfactant solutions I: Sulfathiazole, Prednisone, and Chloramphenicol," *J. Pharm. Sci.* 65:1702-04 (1976).	
		CHRISTENSEN, et al., "Storage of polyvinylpyrrolidone (PVP) in tissues following long-term treatment with a PVP-containing vasopressin preparation," *Act. Med. Scand.* 204:295-98 (1978).	
		CORRIGAN & HOLOHAN, "Amorphous spray-dried hydroflumethiazide-polyvinylpyrrolidone systems: physiochemical properties," *J. Pharm. Pharmacol.* 36(4):217-21 (1984).	
		DE ALMEIDA, et al., "Modeling dissolution of sparingly soluble multisized powders," *J. Pharm. Sci.* 86:726-732 (1997).	
		DORDUNOO, et al., "Physical stability of solid dispersions containing triamterene or temazepam in polyethylene glycols," *J. Pharm. Pharmacol.* 49(4):390-96 (1997).	
		DRESSMAN & FLEISHER, "Mixing-tank model for predicting dissolution rate control or oral absorption," *J. Pharm. Sci.* 75(2):109-16 (1986).	
		EICHMAN & ROBINSON, "Mechanistic studies on effervescent-induced permeability enhancement," *Pharm. Res.* 15(6):925-30 (1998).	
		EL-FATTAH, et al., "Enhancement of dissolution rate of hydrochlorothiazide via solid dispersion," *Pharmazie.* 41(11):790-93 (1986).	
		FEINSTEIN & SCIARRA, "Development and evaluation of a dexamethasone timed-release aerosol formulation," *J. Pharm. Sci.* 64:408-13 (1975).	
		FENIMORE & LOY, "Injectible dispersion of Δ^9-tetrahydrocannabinol in saline using polyvinyl pyrrolidone," *J. Pharm. Pharmac.* 23:310- (1971).	

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		FORD, "The current status of solid dispersions," *Pharm. Act. Helv.* 61:69-88 (1986).	
		FREITAS & MÜLLER, "Spray-drying of solid lipid nanoparticles (SLN™)," *Eur. J. Pharm. Biopharm.* 46(2):145-51 (1998).	
		GALIA, et al., "Evaluation of various dissolution media for predicting *in vivo* performance of class I and II drugs," *Pharm. Res.* 15(5):698-705 (1998).	
		GENTA, et al., "Improvement of dexamethasone dissolution rate from spray-dried chitosan microspheres," *S.T.P. Pharma Sciences* 5(3):202-07 (1995).	
		GHOSH, et al., "Product development studies on the tablet formulation of ibuprofen to improve bioavailability," *Drug Dev. Ind. Pharm.* 24(5):473-77 (1998).	
		GIUNCHEDI, et al., "A swellable polymer as carbamazepine dissolution rate enhancer," *Boll. Chim. Farm.* 129(1):17-20 (1990).	
		GRIJSEELS, et al., "Dissolution at porous interfaces VI: Multiple pore systems," *J. Pharm. Sci.* 73(12):1771-74 (1984).	
		GRIJSEELS, et al., "Dissolution at porous interfaces VI: Pore effects in natural convection flow," *Pharmaceutisch Weekblad Scienific Edition* 5:88-94 (1983).	
		HAMMAD & MÜLLER, "Increasing drug solubility by means of bile salt-phosphatidylcholine-based mixed micelles," *Eur. J. Pharm. Biopharm.* 46(3):361-67 (1998).	
		HASTEDT & WRIGHT, "Diffusion in porous materials above the percolation threshold," *Pharm. Res.* 7(9):893-901 (1990).	

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		HIRSCHBERG, et al., "Oral absorption of CGS-20625, an insoluble drug, in dogs and man," *J. Pharmacokinet. Biopharm.* 23(1):11-23 (1995).	
		HONG, et al., "Accelerated oral absorption of gliclazide in human subjects from a soft gelatin capsule containing a PEG 400 suspension of gliclazide," *J. Controlled Release* 51(2-3):185-92 (1998).	
		IMAI, et al., "Enhancement of the dissolution rates of poorly water-soluble drugs by water-soluble gelatin," *Chem. Pharm. Bull.* 37(8):2251-52 (1989).	
		IMAI, et al., "Rapidly absorbed solid oral formulations of ibuprofen using water-soluble gelatin," *J. Pharm. Pharmacol.* 42(9):615-19 (1990).	
		JU, et al., "Drug release from hydrophilic matrices. 1. New scaling laws for predicting polymer and drug release based on the polymer disentanglement concentration and the diffusion layer," *J. Pharm. Sci.* 84(12):1455-63 (1995).	
		KAGKADIS, et al., "A freeze-dried injectable form of ibuprofen: development and optimisation using response surface methodology," *PDA J. Pharm. Sci. Technol.* 50(5):317-23 (1996).	
		KAI, et al., "Oral absorption improvement of poorly soluble drug using solid dispersion technique," *Chem. Pharm. Bull.* 44(3):568-71 (1996).	
		KANENIWA & WATARI, "Dissolution of slightly soluble drugs. I. Influence of particle size on dissolution behavior," *Chem. Pharm. Bull.* 22:1699-705 (1974).	
		KAUR, et al., "Comparison of polyethylene glycol and polyoxyethylene stearate as excipients for solid dispersion systems of griseofulvin and tolbutamide II: dissolution and solubility studies," *J. Pharm. Sci.* 69(11):1321-26 (1980).	
		KAWASHIMA, et al., "Improvement of solubility and dissolution rate of poorly water-soluble salicylic acid by a spray-drying technique," *J. Pharm. Pharmacol.* 27(1):1-5 (1975).	

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		KHAN & JIABI, "Preparation, characterization, and dissolution studies of ibuprofen solid dispersions using polyethylene glycol (PEG), talc, and PEG-talc as dispersion carriers," *Drug Dev. Ind. Pharm.* 24(5):455-62 (1998).	
		KHAN, et al., "Controlled release coprecipitates: formulation considerations," *J. Control. Rel.* 37:131-41 (1995)	
		KIM & YOON, "Development of digoxin dry elixir as a novel dosage form using a spray-drying technique," *J. Microencapsul.* 12(5):547-56 (1995).	
		KINCL, et al., "Increasing oral bioavailability of progesterone by formulation," *J. Steroid. Biochem.* 9(1):83-84 (1978).	
		KONDO, et al., "Pharmacokinetics of a micronized, poorly water-soluble drug, HO-221, in experimental animals," *Biol. Pharm. Bull.* 16(8):796-800 (1993).	
		KUBO & MIZOBE, "Improvement of dissolution rate and oral bioavailability of a sparingly water-soluble drug, (+/-)-5-[[2-(2-naphthalenylmethyl)-5-benzoxazolyl]-methyl]- 2, 4-thiazolidinedione, in co-ground mixture with D-mannitol," *Biol. Pharm. Bull.* 20(4):460-63 (1997).	
		KUBO, et al., "Enhancement of oral bioavailability and pharmacological effect of 1-(3,4-dimethoxyphenyl)-2,3-bis(methoxycarbonyl)-4-hydroxy-6,7,8- trimethoxynaphthalene (TA-7552), a new hypocholesterolemic agent, by micronization in co-ground mixture with D-mannitol," *Biol. Pharm. Bull.* 19(5):741-47 (1996).	
		LEE, et al., "Mathematical modelling of the release of drug from porous, nonswelling transdermal drug-delivery devices," *IMA J. Math. Appl. Med. Biol.* 15(2):135-63 (1998).	
		LEMOS-SENNA, et al., "Evaluation of the hydrophobic drug loading characteristics in nanoprecipitated amphiphillic cyclodextrin nanospheres," *Pharm. Dev. Tech.* 3:85-94 (1998).	
		LEUCUTA, et al., "The kinetics of nifefipine release from porous hydrophilic matrices and the pharmacokinetics in man," *Pharmazie* 43:845-48 (1988).	

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		LIN, et al., "Improved oral absorption of L-365260, a poorly soluble drug," *Biopharm. Drug Dispos.* 17(1):1-15 (1996).	
		LIN, et al., "Preparation of enteric-coated microspheres of *Mycoplasma hyopneumoniae* vaccine with cellulose acetate phthalate: (II). Effect of temperature and pH on the stability and release behaviour of microspheres," *J. Microencapsul.* 8(4):537-45 (1991).	
		MARTINDALE, The Extra Pharmacopoeia, 711 Dissolution, pp. 1791-92, 30th Ed. (The Pharmaceutical Press, London 1993).	
		MASON & WINER, "Kinetics of aspirin, salicylic acid, and salicyluric acid following oral administration of aspirin as a tablet and two buffered solutions," *J. Pharm. Sci.* 70(3):262-65 (1981).	
		MIGLIARESI, et al., "Physical characterization of microporous poly(2-hydroxyethyl methacrylate) gels," *J. Biomed. Mater. Res.* 15:307-17 (1981).	
		MISHRA & YALKOWSKY, "A flat circular hole device for zero-order release of drugs: characterization of the moving dissolution boundary," *Pharm. Res.* 7(11):1195-97 (1990).	
		MORRIS, et al., "Structural properties of polyethylene glycol-polysorbate 80 mixture, a solid dispersion vehicle," *J. Pharm. Sci.* 81(12):1185-88 (1992).	
		NAJIB, et al., "The adsorption of hydrophilic polymers at the liquid-solid interface," *J. Pharm. Pharmac.* 29:43P (1977).	
		NISHIMURA, et al., "Dosage form design for improvement of bioavailability of levodopa VI: formulation of effervescent enteric-coated tablets," *J. Pharm. Sci.* 73(7):942-46 (1984).	
		NYSTRÖM & WESTERBERG, "The use of ordered mixtures for improving the dissolution rate of low solubility compounds," *J. Pharm. Pharmacol.* 38(3):161-65 (1986).	

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Complete if Known	
Application Number	10/053,929
Filing Date	January 22, 2002
First Named Inventor	Julie Straub
Group Art Unit	
Examiner Name	
Attorney Docket Number	ACU 109 CIP

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		NYSTRÖM, et al., "Dissolution rate measurements of sparingly soluble compounds with the Coulter Counter model TAII," *J. Pharm. Pharmacol.* 37(4):217-21 (1985).	
		OTSUKA, et al., "Hygroscopic stability and dissolution properties of spray-dried solid dispersions of furosemide with Eudragit," *J. Pharm. Sci.* 82(1):32-38 (1993).	
		PACE, et al., "Novel injectable formulations of insoluble drugs," *Pharmaceutical Technology* 116-34 (March 1999).	
		PILLAY & FASSIHI, "A new method for dissolution studies of lipid-filled capsules employing nifedipine as a model drug," *Pharm. Res.* 16(2):333-37 (1999).	
		REDDY, et al., "Dissolution characteristics and oral absorption of digitoxin and digoxin coprecipitates," *J. Pharm. Sci.* 65(12):1753-58 (1976).	
		RIDOLFO, et al., "Benoxaprofen, a new anti-inflammatory agent: particle-size effect on dissolution rate and oral absorption in humans," *J. Pharm. Sci.* 68(7):850-52 (1979).	
		SAANO, et al., "Relative pharmacokinetics of three oral 400 mg ibuprofen dosage forms in healthy volunteers," *Int. J. Clin. Pharm. Ther. Toxic.* 29:381-85 (1991).	
		SCHRÖDER & SABEL, "Nanoparticles, a drug carrier system to pass the blood-brain barrier, permit central analgesic effects of i.v. dalargin injections," *Brain Research* 710:121-24 (1996).	
		SERAJUDDIN, et al., "Effect of vehicle amphiphilicity on the dissolution and bioavailability of a poorly water-soluble drug from solid dispersions," *J. Pharm. Sci.* 77(5):414-17 (1988).	
		SERAJUDDIN, et al., "Improved dissolution of a poorly water-soluble drug from solid dispersions in polyethylene glycol: polysorbate 80 mixtures," *J. Pharm. Sci.* 79(5):463-64 (1990).	

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		SERAJUDDIN, et al., "Water migration from soft gelatin capsule shell to fill material and its effect on drug solubility," *J. Pharm. Sci.* 75(1):62-64 (1986).	
		SUZUKI & SUNADA, "Comparison of nicotinamide, ethylurea, and polyethylene glycol as carriers for nifedipine solid dispersion systems," *Chem. Pharm. Bull.* 45:1688-93 (1997).	
		SUZUKI & SUNADA, "Influence of water-soluble polymers on the dissolution of nifedipine solid dispersions with combined carriers," *Chem. Pharm. Bull.* 46:482-87 (1998).	
		SWEETANA & AKERS, "Solubility principles and practices for parenteral drug dosage form development," *PDA J. Pharm. Sci. Technol.* 50(5):330-42 (1996).	
		TAKENAKA, et al., "Preparations of solid particulates of theophylline--ethylenediamine complex by a spray-drying technique," *J. Pharm. Sci.* 71(8):914-19 (1982).	
		TAKEUCHI, et al., "Enhancement of the dissolution rate of a poorly water-soluble drug (tolbutamide) by a spray-drying solvent deposition method and disintegrants," *J. Pharm. Pharmacol.* 39(10):769-73 (1987).	
		TASIĆ, et al., "The influence of beta-cyclodextrin on the solubility and dissolution rate of paracetamol solid dispersions," *J. Pharm. Pharmacol.* 44(1):52-55 (1992).	
		TINGSTAD, et al., "Dissolution rate studies. III. Effect of type and intensity of agitation on dissolution rate," *J. Pharm. Sci.* 62(2):293-97 (1973).	
		TORRADO, et al., "Egg albumin microspheres containing paracetamol for oral administration. I. In vitro characterization," *J. Microencapsul.* 7(4):463-70 (1990).	
		TRAUE, et al., "Spray products of sparingly soluble drugs. 1. In vitro study of spray products of nitrazepam in a starch hydrolysis product," *Pharmazie.* 43(5):368-69 (1988).	

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		VÉLAZ, et al., "Effect of PEG 4000 on the dissolution rate of naproxen," *Eur. J. Drug Metab. Pharmacokinet.* 23(2):103-08 (1998).	
		VENKATARAM & ROGERS, "Characteristics of drug-phospholipid coprecipitates I: Physical properties and dissolution behavior of griseofulvin-dimyristoylphosphatidylcholine systems," *J. Pharm. Sci.* 73(6):757-61 (1984).	
		VUDATHALA & ROGERS, "Dissolution of fludrocortisone from phospholipid coprecipitates," *J. Pharm. Sci.* 81(3):282-86 (1992).	
		WAN, et al., "Plasticizers and their effects on microencapsulation process by spray-drying in an aqueous system," *J. Microencapsul.* 9(1):53-62 (1992).	
		WESTERBERG, et al., "Physicochemical aspects of drug release. IV. The effect of carrier particle properties on the dissolution rate from ordered mixtures," *Int. J. Pharm.* 28:23-31 (1986).	
		YAMAOKA, et al., "Comparison of body distribution of poly(vinyl alcohol) with other water-soluble polymers after intravenous administration," *J. Pharm. Pharmacol.* 47:479-86 (1995).	
		YAMAOKA, et al., "Fate of water-soluble polymers administered via different routes," *J. Pharm. Sci.* 84(3):349-54 (1995).	

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